UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,537	01/19/2006	Michael Melkonian	1020-018US01	9911

28863 7590 05/18/2007
SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER	
KIM, TAEYOON	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,537	MELKONIAN ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *8-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/2/06, 7/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are pending.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-7) in the reply filed on March 6, 2007 is acknowledged. The traversal is on the ground(s) that the restriction requirement failed to meet the requirement in M.P.E.P. §803. This is not found persuasive. It is reminded that the restriction requirement of the instant application is under the discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules, rather than the requirement under 35 U.S.C. 111(a). See M.P.E.P. §1805. Applicant alleges that there would be no burden on the examiner in examining all of the claims at once, however, is also limited to a discussion of the subject of restriction and double patenting under Title 35 of the United States Code and Title 37 of the Code of Federal Regulations as it relates to national applications filed under 35 U.S.C. 111(a). The discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules as it is applied as an International Searching Authority, International Preliminary Examining Authority, and in applications entering the National Stage under 35 U.S.C. 371 as a Designated or Elected Office in the U.S. Patent and Trademark Office is covered in M.P.E.P. §1850 and is dictated by PCT Rules 13.1 and 13.2. See M.P.E.P. §801. Burden is not a consideration in a finding of lack of inventive unity; rather, according to M.P.E.P. §1850, the only consideration is whether the inventions share a special technical feature.

Applicant also alleged that the examiner oversimplified the common feature between two independent claims (claim 1 and 8) and there are many features that may

distinguish the prior art, and may provide a unifying concept. Although the argument may be reasonable, and the examiner extends the common technical feature shared between Group I and II invention of the instant application, still unity of invention is lacking. Upon the further consideration, the examiner determined that the common technical feature shared between Group I and II inventions is "a device for cultivating eukaryotic microorganism comprising a perforated support having two surfaces and the microorganism is immobilized in one surface for culture". This common technical feature is not considered as "special technical feature" because Halling et al. (WO 90/02170; IDS reference) teach a device for culturing plant and animal cells having a porous membrane impermeable for microorganisms applied to a first main surface whereas liquid flows along the second major surface (see Fig. 1-3). Thus, the common technical feature of "a device for cultivating eukaryotic microorganism comprising a perforated support having two surfaces and the microorganism is immobilized in one surface for culture" between Group I and II inventions is not considered "specific technical feature", therefore, unity of invention is lacking.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-17 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-7 have been considered on the merits.

Claim Objections

Claims 2-5 are objected to because of the following informalities: claim 2 discloses a subject matter of "distribution layer". Since the specification discloses the later as "distributing layer", applicant is advised to amend the term in the claims to be consistent with the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claims, there are numerous parenthesized numbers, which appear to indicate numbers shown in Drawings of the current application. However, without specific definition and/or indication that these numbers are pointing out the numbers shown in the Drawings, these parenthesized numbers are indefinite.

Furthermore, the claims are drawn to a method. However, the current claims clearly describe and claim to an apparatus as the parenthesized numbers indicate parts of the apparatus in drawings. A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. §112, second paragraph. IPXL Holdings v. Amazon.com, Inc., 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005); Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) (claim directed to an automatic transmission workstand and the method of using it held ambiguous and properly rejected under 35 U.S.C. 112, second paragraph).

The phrase "a web material" in claim 1 is not clear what this phrase intends to point out. It is indefinite whether the perforated support is made of "a web material", it is shaped like a web material, or it contains a web material as a separate structural component of the support. According to the specification, there are two possible

interpretations to the limitation. It is described in p. 4 of the specification that "the support layer," which is referred to as support, is made of a web material. However, in p.6 of the specification, the support is described as being perforated and web-shaped.

The phrase "in particular" in the claims is considered as "preferred" conditions, which do not precisely define the metes and bounds of the claims. It is not clear whether any conditions other than the recited conditions are part of the claimed invention.

One of steps in the method of claim 1 discloses a limitation of "an aqueous solution flows along the first major surface (22)". This limitation is not clear whether the flow of the solution is parallel to the first surface or the solution is actually flowing on the first major surface. In addition, the parenthesized number (22) according to the figure appears to be the second major surface rather than the first surface. For examination purpose, the limitation is interpreted as "an aqueous solution flows along the second major surface".

Claim 2 recites the limitation "the layer" in line 1. There is insufficient antecedent basis for this limitation in the claim.

The phrase "of the or" in claim 2, line 3, is indefinite because it appears that there is missing subject matter after the article "the".

Claims 4 and 5 recite the limitation "the further perforated support" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The phrase "if present" in claims 4 and 5 is not clear what subject matter the phrase intends to point out. It can be interpreted that the limitation is only to 1) one of the perforated support, a further perforated support or the distribution layer, or 2) all three of the perforated support, a further perforated support and the distribution layer. If

the limitation is drawn to all three (the perforated support, a further perforated support and the distribution layer) listed, this limitation can be read as if those three would not be present. If that were the case, the method would not be enabling. Clarification of the phrase is required.

Regarding claim 7, the phrase "e.g. (for example)" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 7 is drawn to a harvesting step after culturing microorganisms or blue algae by various methods. However, the means of harvesting biomass listed as a Markush group is not clear. First option is listed as to remove biomass by mechanical forces; the second option is the biomass is harvested together with the support; the third option is to remove biomass in flowing culture medium, and the fourth option is to dry the biomass and collect them. These Markush groups are not listed as an alternative way. Instead, the current claim utilizes the term “and/or”. Applicant is advised to amend the claim to have a proper Markush group.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al. (US 4,693,983).

Claims 1-6 are drawn to a method for cultivating eukaryotic microorganisms comprising providing a perforated support having first and second major surface wherein the support being shaped like a web material and being impermeable to eukaryotic microorganisms or blue algae, applying the eukaryotic microorganisms or blue algae to the first major surface wherein the microorganisms being removably immobilized, flowing an aqueous solution along the first major surface, wherein the flowing aqueous solution being transported to the first major surface by capillary forces, and the eukaryotic microorganisms or blue algae grow on the first major surface (claim 1); a limitation to the aqueous solution forming a distribution layer to distribute the solution across the second major surface of each perforated support (claim 2); a limitation to the distribution layer being a non-woven material (claim 3); a limitation to the support and/or layer being hydrophilic (claim 4); a limitation to the support and/or layer comprising mineral fibers, hydrophilic organic fibers, organic or inorganic materials (claim 5); a limitation to the method further comprising additional support identical configuration of the support, wherein two supports having the second major surface facing each other and arranged being in parallel to each other, and the aqueous solution being introduced and flowing between the two supports in contact with the second surfaces (claim 6).

Davies et al. teach a method using a reactor for cultivating plant or animal cells. The reactor of Davies et al. comprising a perforated support having two channel (surface) wherein biological materials (plant or animal cells) bound to walls of first

channel impermeable to the material, and the liquid and/or gas (nutrients) are transferred between the first channels and the second channels through porous walls (see Fig. 1 and column 2, lines 1-18). The transferred of liquid (nutrients) through the porous walls is inherently carried out by capillary forces because Davies et al. teach the porous wall having a capillary connection between channels (see. Fig. 4). The bioreactor of Davies et al. comprises multiple channels formed like a web material and first major surfaces (channels where cells are immobilized) face each other and share with one second major surface (channel) whereby liquid can flow between two facing first major surfaces (see Fig. 1). Furthermore, the matrix support of Davies et al.'s bioreactor is made of ceramic material which has been leached in an acid or alkali to render the interior walls porous (see column 3, lines 47-50). Thus, the support of Davies et al. is a porous, web material by itself and also the whole structure is web-shaped. Davies et al. also disclose porous cells being treated with a semi-permeable membrane such as cellulose acetate, which inherently hydrophilic (distribution layer of a non-woven material) (see column 3, lines 57-61).

Thus, the reference anticipates the claimed subject matter.

Claims 1 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Halling et al. (WO 90/02170).

Claims 1 and 4-5 are drawn to a method for cultivating eukaryotic microorganisms comprising providing a perforated support having first and second major surface wherein the support being shaped like a web material and being impermeable to eukaryotic microorganisms or blue algae, applying the eukaryotic

microorganisms or blue algae to the first major surface wherein the microorganisms being removably immobilized, flowing an aqueous solution along the first major surface, wherein the flowing aqueous solution being transported to the first major surface by capillary forces, and the eukaryotic microorganisms or blue algae grow on the first major surface (claim 1); a limitation to the support and/or layer being hydrophilic (claim 4); a limitation to the support and/or layer comprising mineral fibers, hydrophilic organic fibers, organic or inorganic materials (claim 5).

Halling et al. teach a method and an apparatus (membrane bioreactor) for culturing microbial cells (plant and animal cells) immobilized on the outside (shell side; first major surface) of a membrane through which a culture medium can flow (inside of the membrane; tube side; second major surface), and through a support matrix surrounding the membrane (see Abstract, p.1, line 3; p.1, line 33-p.2, line 3; p.2 line 36 to p.3, line 4; and Fig. 1-3). The material of perforated support of Halling et al. is a macroporous ceramic material (see p.2, line 5), which is inorganic and inherently hydrophilic.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (supra).

Claims 1-7 are drawn to a method for cultivating eukaryotic microorganisms comprising providing a perforated support having first and second major surface wherein the support being shaped like a web material and being impermeable to eukaryotic microorganisms or blue algae, applying the eukaryotic microorganisms or blue algae to the first major surface wherein the microorganisms being removably immobilized, flowing an aqueous solution along the first major surface, wherein the flowing aqueous solution being transported to the first major surface by capillary forces, and the eukaryotic microorganisms or blue algae grow on the first major surface (claim 1); a limitation to the aqueous solution forming a distribution layer to distribute the solution across the second major surface of each perforated support (claim 2); a limitation to the distribution layer being a non-woven material (claim 3); a limitation to the support and/or layer being hydrophilic (claim 4); a limitation to the support and/or layer comprising mineral fibers, hydrophilic organic fibers, organic or inorganic materials

(claim 5); a limitation to the method further comprising additional support identical configuration of the support, wherein two supports having the second major surface facing each other and arranged being in parallel to each other, and the aqueous solution being introduced and flowing between the two supports in contact with the second surfaces (claim 6); a limitation to the method of claim 1 further comprising a step of removing the microorganisms or blue algae after cultivation by mechanical forces, together with the support, in flowing culture medium, or dry (claim 7).

Davies et al. anticipate the subject matter of claims 1-6, and thus render them obvious (see above).

Although Davies et al. do not particularly teach a step of harvesting method listed in claim 7, it would have been obvious for a person of ordinary skill in the art to recognize the need of harvesting cells grown in the bioreactor of Davies et al. by using mechanical forces, for example. In fact, Davies et al. teach that cells grown in a first major surface can be removed by flushing (see column 4, lines 57-62), indicating that the step of harvesting cells grown in Davies et al.'s bioreactor can be mechanically collected from the support matrix.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Patent Examiner
Art Unit 1651

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651